

REMARKS

I. Status of Claims

Applicants submit this Amendment in reply to the Office Action mailed September 8, 2009.

By this Amendment, Applicants amend claims 11, 35, 50, 57, 58, and 89, and add new claims 104-106. The originally-filed specification, drawings, and claims fully support the subject matter of amended claims 11, 35, 50, 57, 58, and 89 and new claims 104-106.

Before entry of this Amendment, claims 1, 2, 6-27, 31-50, 52-65, and 87-103 were pending in this application, with claims 91-94 having been withdrawn from consideration. After entry of this Amendment, claims 1, 2, 6-27, 31-50, 52-65, and 87-106 are pending in this application. Independent claims 1, 11, 26, 35, 50, and 91 are the sole independent claims.

II. Election/Restriction of Claims

On page 2, the Office Action alleged that claims 91-94 are directed to an invention distinct from an invention originally claimed, and that Applicants have elected to prosecute the originally-claimed invention by original presentation. The Office Action then withdrew claims 91-94 from consideration. Applicants respectfully traverse the restriction by original presentation for at least the following reasons.

Applicants call attention to 37 C.F.R. § 1.145, which provides:

[i]f, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered,

subject to reconsideration and review as provided in §§ 1.143 and 1.144.

(Emphasis added.) MPEP § 806.05(j) states “[t]o support a requirement for restriction between two or more related product inventions ... both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search,” and “[t]he burden is on the examiner to provide an example to support the determination that the inventions are distinct.”

Here, the Office has failed to clearly articulate reasons for the restriction by original presentation and provide support for the determination that the claims are distinct. Indeed, the Office failed to address any of the requirements for distinctiveness provided by MPEP § 806.05(j). Additionally, the Office provided no showing of separate classification, status in the art, or field of search. Instead, the Office Action generally concluded that claim 91-94 are distinct from the remaining independent claims because “[i]ndependent claims 1, 26, 50 recite that the cutter is engaged with a recess on the holder and the storage portion is engaged with a recess on the holder. Claims 91-94 recite that the cutting portion is engaged via a recess and protrusion with the storage portion.”¹ See page 2 of the Office Action. Accordingly, the requirement for restriction does not conform to Office practice as outline in the MPEP and should be withdrawn.

Furthermore, even assuming *arguendo* that the various inventions recited in the pending claims are themselves distinct (which Applicants do not necessarily concede), the Office Action has failed to establish a search and examination of all the claims

¹ Applicants note that, prior to this Amendment, claim 50 included no recitation of a cutter “engaged with a recess on the holder and the storage portion [] engaged with a recess on the holder.”

cannot be made without serious burden. See MPEP § 803. In fact, the Office Actions of February 5, 2009, July 11, 2008, and December 7, 2007 indicate that claims 91-94 have been searched and examined on the merits. The Office's willingness to examine claims 91-94, which still remain in original form, demonstrates a lack of a "serious search burden."

For at least the above reasons, Applicants respectfully request withdrawal of the restriction by original presentation and continued examination of claims 91-94.

III. Section 112, Second Paragraph Rejection

On page 3 of the Office Action, claims 57 and 58 were rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. More particularly, page 2 of the Office Action asserts that "[c]laims 57 and 58 recite the limitation 'the end effector portion.' There is insufficient antecedent basis for this limitation in the claim[s]." See page 3 of the Office Action. Applicants have amended claims 57 and 58 to overcome this rejection.

IV. Section 103(a) rejection based on a combination of Cohen, Krzyzanowski and Slater

On page 3 of the Office Action, claims 1, 2, 6-12, 14, 15, 17-27, 31-39, 41-44, and 95-96 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Application 2005/0054945 to Cohen et al. ("Cohen") in view of U.S. Patent No. 6,440,085 to Krzyzanowski ("Krzyzanowski"); on page 6 of the Office Action, claims 16, 40, 87, and 88 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Krzyzanowski, as applied to claims 1 and 26, and further in view of U.S. Patent No. 5,482,054 to Slater ("Slater"); and on page 7 of the Office Action, claims 50,

52-65, 90, and 97-103 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohen, Krzyanowski, and Slater. Applicants respectfully traverse these rejections.

The Cohen reference was published on March 10, 2005, which is after November 25, 2003, the filing date of the instant application. Because Cohen is being relied upon as prior art under 35 U.S.C. § 102(e), Applicants respectfully submit that under the provisions of 35 U.S.C. § 103(c), the Section 103(a) rejections based on Cohen can be overcome by showing that the subject matter of the Cohen reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See M.P.E.P. § 706.02(L)(2)(II). Applicants therefore supply a statement on a separate sheet of this response, made by Applicants' representatives, regarding the ownership of this application and the Cohen reference.

Without in any way conceding the appropriateness of the Section 103 rejections, Applicants respectfully submit that, in light of this statement, the Section 103(a) rejections utilizing Cohen should be withdrawn.

Applicants' Representative of Record Statement of
Common Ownership Under M.P.E.P. §706.02(I)(2)

Under the provisions of M.P.E.P. §706.02(I)(2), Applicants' undersigned representative of record supplies the following statement to the effect that this application and the Cohen publication (U.S. Patent Application Publication 2005/0054945) were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same organization:

This application, U.S. Patent Application No. 10/720,668, filed November 25, 2003, in the name of Otto E. Anderhub et al., and U.S. Patent Application Publication 2005/0054945, filed as U.S. Application No. 10/658,261 on September 10, 2003, in the name of Adam L. Cohen et al. were, at the time the invention of this application was made, both owned or subject to an assignment to Scimed Life Systems, Inc. (now Boston Scientific Scimed, Inc.).

V. Section 103(a) rejection based on Krzyzanowski and Caisley

On page 9 of the Office Action, claims 1, 2, 6-11, 13-15, 17-27, 31-35, 37-39, 42-46, 48, 95, and 96 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzyzanowski in view of International Publication No. WO 02/39810 A2 to Caisley (“Caisley”). Applicants respectfully traverse the rejection.

No combination of Krzyzanowski and Caisley discloses or suggests the claimed invention. For example, independent claim 1 recites an end effector assembly for obtaining multiple tissue samples comprising, among other things, a cutting portion, a holder, and a storage portion, “wherein the holder is configured to receive both the cutting portion and the storage portion, wherein the holder has a groove for receiving both a protrusion on the cutting portion and a protrusion on the storage portion.” Independent claim 26 includes similar recitations. No combination of Krzyzanowski and Caisley discloses or suggests at least this aspect of the claimed invention either alone or in combination with other aspects of each of respective claims 1 and 26.

In utilizing Krzyzanowski as the primary reference to reject independent claims 1 and 26, page 9 of the Office Action points to edge 27 as corresponding to the claimed “cutting portion” and lower jaw 26 as corresponding to the claimed “holder.” The Office Action asserts that the groove in lower jaw 26, shown best in Fig. 3, corresponds to the claimed “groove.” While the Office Action concedes that “Krzyzanowski’085 does not teach a removable storage portion having a protrusion that is received by a groove on the holder,” the Office Action asserts that Caisley discloses a sample container with a protrusion that engages a groove on an alleged holder to create a removable storage container. See page 9 of the Office Action. Therefore, the Office Action contends “[i]t

would have been obvious to one of ordinary skill in the art to modify the device of Krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient."

See page 9 of the Office Action. Applicants respectfully disagree.

One skilled in the art would not be motivated to modify the Krzyzanowski device to include the sample container from Caisley. Caisley discloses a system for tagging a biological object having a sample container 1 received in and detachable from a collar member 15. See Fig. 4. In particular, Caisley teaches that the edge 45 of the enlarged rim on sample container 1 is received by a lateral groove formed in collar 15. See pages 9, line 37 through page 10, line 38; and Fig. 3. Applicants are unclear how the device of Krzyzanowski may be modified with the sample container from the Caisley device so that edge 45 of the enlarged rim of sample container 1 may be received in the alleged groove of Krzyzanowski. The very position of the alleged groove of Krzyzanowski appears unable to accept any protrusions parallel to a plane containing opening in lower jaw 26, like edge 45 of the enlarged rim on sample container 1 of the Caisley device. The alleged groove in lower jaw 26 of the Krzyzanowski device, best seen in Fig. 3, only appears to accommodate vertical protrusions received from the top of jaw 30.

Furthermore, even if the protrusion were directed at the alleged groove of Krzyzanowski, the alleged groove would be unable to accommodate "both a protrusion on the cutting portion and a protrusion on the storage portion," as required by independent claims 1 and 26. More particularly, Krzyzanowski teaches that edge 27 is either insert molded or snap fit into the alleged groove in lower jaw 26. In the

assembled state of Fig. 7, the groove appears to be unable to accept a protrusion from another element in addition to edge 27. Therefore, absent improper hindsight, one skilled in the art would not have any reason to modify the Krzyzanowski device to include the sample container from Caisley.

Applicants respectfully request the reconsideration and withdrawal of the Section 103 rejection of claims 1 and 26 based on Krzyzanowski and Caisley.

VI. Section 103(a) rejection based on Krzyzanowski, Caisley, and Slater

On page 10 of the Office Action, claims 1, 16, 26, 40, 50, 52-62, 64, 90, and 97-103 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krzyzanowski in view of Caisley in view of Slater. Applicants respectfully traverse the rejection.

As discussed above, no combination of Krzyzanowski and Caisley disclose the combinations of independent claims 1 and 26. In formulating this rejection, the Office has relied upon Slater only for the teaching of a holder having a non-straight portion. Even if the combination of Krzyzanowski and Caisley were modified by the teaching of Slater, that modified device would not meet the claimed combination. Therefore, for at least the reasons stated above, Applicants request reconsideration and withdrawal of the Section 103(a) rejection of claims 1 and 26 based on Krzyzanowski, Caisley, and Slater.

With regard to independent claim 50, no combination of Krzyzanowski, Caisley, and Slater disclose the claimed combination. For example, independent 50 recites an endoscopic instrument comprising, among other aspects, “wherein the second end effector has a non-straight portion connecting a tang to a cutting edge and configured to be received in a correspondingly-shaped gap in the holder, and wherein the holder has

a groove closer to a bottom of the holder than a top of the holder to receive an edge of the end effector, when the non-straight portion is receive in the correspondingly-shaped gap in the holder.” No combination of Krzyzanowski, Caisley, and Slater discloses or suggests at least this aspect of the claimed invention either alone or in combination with other aspects of independent claim 50.

Page 11 of the Office Action acknowledges that Krzyzanowski and Caisley “do not teach a non-straight portion connecting a tang to a cutting edge.” The Office Action, however, relies on Slater for the alleged teaching of “a cutter (418; Fib 8b) with a non-straight portion (portion 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c).” See page 11 of the Office Action.

As an initial matter, Applicants note that page 11 of the Office Action has cited no factors that would have motivated one skilled in the art to modify the disclosures thereof to achieve the claimed combination. Therefore, a *prima facie* case of obviousness has not been established with respect to claim 50 because the Office Action has failed to articulate a reason why the claim would have been obvious to one skilled in the art.

Nonetheless, in order to expedite prosecution in the case, Applicants amend claim 50 to recite “wherein the holder has a groove closer to a bottom of the holder than a top of the holder to receive an edge of the second end effector, when the non-straight portion is received in the correspondingly-shaped gap in the holder.” While Krzyzanowski may disclose a groove adjacent the top of jaw 26, Krzyzanowski fails to disclose a groove closer to the bottom than a top of the holder to receive a protrusion on

the second end effector, when the non-straight portion is received in the correspondingly-shaped gap in the holder. Neither Caisley nor Slater cure the deficiency of Krzyzanowski in such a way that they would render the subject matter of the present invention obvious.

Accordingly, Applicants request reconsideration and withdrawal of the Section 103(a) rejection of claim 50 based on Krzyzanowski, Caisley, and Slater.

VII. Dependent Claims

Applicants further submit that claims 2, 6-10, 12-25, 27, 31-24, 36-49, 52-65, and 87-90 depend either directly or indirectly from one of independent claims 1, 26, and 50, and are therefore allowable for at least the same reasons that independent claims 1, 26, and 50 are respectively allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references, and therefore at least some also are separately patentable.

VIII. New Claims

New independent claim 11 recites an end effector assembly for obtaining multiple tissue samples including, among other aspects “wherein both the cutting portion and the holder are comprised of metal.” New independent claim 35 includes similar recitations. On page 11 of the Office Action, the Office asserts that the material of the different components “is nothing more than an obvious design choice.” Applicants respectfully disagree. In stark contrast to the claim, Krzyzanowski is directed to a method of assembly of non-metallic biopsy forceps jaws. For example, the entire disclosure, including abstract and claims, is directed to non-metallic biopsy forceps jaws. While Krzyzanowski does disclose that the cutting edge may be composed of metal,

Krzyzanowski makes clear that the remainder of the jaw is composed of non-metallic materials. Indeed, Krzyzanowski explains the alleged disadvantages of having a metallic biopsy jaws. For example, according to Krzyzanowski, methods of making devices with metallic components “require[] meticulous effort to align and secure the metallic components of the jaw. This results in costly and time consuming assembly.” See col. 1, lines 24-26 of Krzyzanowski. Therefore, Krzyzanowski teaches that “[a]n object of one aspect of the present invention is to provide an improved method of assembly of a non-metallic biopsy forceps jaw device and a non-metallic biopsy forceps jaw.” See col. 1, lines 61-64 of Krzyzanowski. Krzyzanowski also teaches the alleged “[a]dvantage of [its] invention [to] include the use of non-metallic materials for the biopsy jaws thereby allowing the snap-connections of the upper and lower jaws and the activating wires with the jaws ... Furthermore, the use of non-metallic components makes the device cheaper and therefore disposable if desired.” See col. 2, lines 44-55 of Krzyzanowski. Therefore, contrary to the allegations of the Examiner, one skilled in the art would not have found it an obvious matter of design choice to have both the cutting portion and the holder comprised of metal as recited in new independent claims 11 and 35. One skilled in the art, when reading Krzyzanowski, instead would comprise components of non-metallic materials.

IX. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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